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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/532,196   | 04/21/2005  | Choon-Gon Jang       | F-8647              | 8403             |
| 28107  | 7590        | 09/15/2006           | EXAMINER            |                  |
| JORDAN AND HAMBURG LLP<br>122 EAST 42ND STREET<br>SUITE 4000<br>NEW YORK, NY 10168 |             |                      | CHU, YONG LIANG     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1626                |                  |

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/532,196             | JANG ET AL.         |  |
|                              | Examiner<br>Yong Chu   | Art Unit<br>1626    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 July 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 is/are pending in the application.  
 4a) Of the above claim(s) 1,2,5 and 6 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,4, 7, and 8 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 4/21/2005 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 5-8 are added by Amendment filed on 21 April 2005. Claim 1 is amended by the Amendment. Therefore, claims 1-8 are currently pending in the instant application.

### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement, filed on 21 April 2005 has been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

### ***Priority***

This application is a 371 of PCT/KR03/02280 filed on 27 October 2003, and claims the benefit of Republic of Korea Patent Applications 10-2002-0066029, filed on 29 October 2002, and 10-2003-0060353, filed on 29 August 2003.

### ***Response to Lack of Unity***

The response to the restriction request with provisionally election of Group II (claims 3-4, and 7-8) *with traverse* by Applicants' representative, Frank J. Jordan dated on 17 July 2006, has been considered. The traversal is on the ground(s) that the Group I and II of claims are so directly related to each other that it is believed that all of the claims may properly be included in the same application. This is not found persuasive because Group I and Group II are distinct from each other. They have

different utilities (i.e. inhibiting psychological dependence on morphine vs. tolerance to analgesic effects of morphine). Therefore, the requirement is still deemed proper.

### ***Status of the Claims***

Claims 1-2, and 3-4 are further withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) as result of the restriction requirement. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Therefore, claims 3-4, and 7-8 are ready for examination.

### ***Specification***

The disclosure is objected to because of the following informalities: the definitions of abbreviations (e.g. DW/Sal, DW/Mor5, etc.) in Fig.1-4 are not included.

On line 2 page 5 of the Specification, Fig. 3 should be Fig. 4.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). In the present instance, claims 3-4 and 7-8 recite the broad recitation preventing, and the claim also recites inhibiting which is the narrower statement of the range/limitation. Applicant is suggested to keep either one of the terms "preventing" and "inhibiting".

***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, and 4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Korean Pat. No. 10-0281003 as being admitted on line 23-23 page 3 of the Specification.

Applicants' claims relate to a pharmaceutical composition for preventing or inhibiting development of tolerance to analgesic effects of morphine, comprising berberine as an effective ingredient.

Korean Pat. No.10-0281003, as admitted in the Specification discloses a pharmaceutical composition, comprising protoberberine alkaloids as effective ingredients.

The intent to use of the pharmaceutical composition is different between the prior art and the instant application. However, the intent to use adds no patentable weight on the composition, which comprises berberine as an effective ingredient.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. U.S. Pat. 6,692,777.

Applicants' claims relate to a pharmaceutical composition for preventing or inhibiting development of tolerance to analgesic effects of morphine, comprising berberine as an effective ingredient.

Lee et al. discloses a pharmaceutical composition in claims 1-2 of U.S. Pat. 6,692,777, comprising Coptis Rhizoma as an active ingredient. The Specification on paragraph [0026] page 3 further defines that Coptis Rhizoma's active ingredients are berberine.

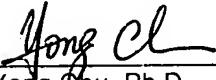
No claims are allowed.

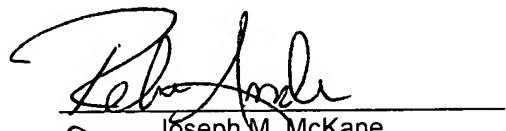
#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
Yong Chu, Ph.D.  
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\_\_\_\_\_  
For Joseph M. McKane  
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